

when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and that frequent or continued use might result in dependence upon laxative; (2) in that the statements (carton) "Female Pills" and (slip in box) "Take one pill three times daily for four or five days previous to expected period," were false and misleading since they created the impression that it would be effective in promoting the menstrual flow, whereas it would not be so effective.

On July 22, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

814. Misbranding of Stevens Concentrated Mineral Water. U. S. v. 67 Bottles of Stevens Concentrated Mineral Water. Default decree of condemnation and destruction. (F. D. C. No. 7522. Sample 87789-E.)

On May 15, 1942, the United States attorney for the District of Columbia filed a libel against the above-named product at Washington, D. C., alleging that the article had been shipped in interstate commerce on or about March 2, 1942, by E. A. Stevens, from Dawson Springs, Ky.

Analysis of a sample of the article showed that it consisted essentially of water, magnesium sulfate, calcium sulfate and small proportions of sodium sulfate, sodium chloride, calcium carbonate, and potassium chloride.

The article was alleged to be misbranded (1) in that its labeling failed to bear adequate directions for use since it was a laxative and the directions provided for continuous administration, whereas a laxative should not be used continuously; (2) in that its labeling failed to warn that a laxative should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and failed to warn that its frequent or continued use might result in dependence upon a laxative; and (3) in that statements in the labeling which represented and suggested that it had given remarkable results for years in many of the ailments of the human system, was efficacious as a regulator and would be efficacious to maintain and restore health, would be efficacious in the treatment of liver, kidney, and stomach trouble, dropsical trouble, rheumatism, malaria, and poor appetite, loss of weight, nervousness, headaches, gas on the stomach, sleeplessness, pains in the legs and a generally depressed condition of the spirits, stomach trouble, constipation, pains in the side, gall-bladder trouble, dead liver, chronic gastric, prostrated gland suffering, flu, run-down condition, acute and chronic nephritis, bedema, dyspnoea and anasarca with indications for the elimination of both fluids and toxins to prevent uremia, engorged condition of the liver or kidneys, gout or any of the uric acid diatheses, bilious conditions, jaundice, intestinal derangements, anemias chlorosis, all blood and constitutional diseases, sluggish portal circulation, coated tongue, and sallow complexion, were false and misleading since the article would not be efficacious for such purposes.

On June 29, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

815. Adulteration and misbranding of milk of magnesia. U. S. v. Certified Pharmacal Co., Inc. Plea of guilty. Fine, \$40. (F. D. C. No. 6461. Sample No. 53412-E.)

On June 30, 1942, the United States attorney for the Southern District of New York filed an information against the Certified Pharmacal Co., Inc., New York, N. Y., alleging shipment on or about December 9, 1940, and June 19, 1941, from the State of New York into the State of California, of quantities of milk of magnesia which was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, and its strength differed from and its quality fell below the standard set forth therein, since samples taken from each of the two shipments showed the presence of 5.85 percent and 5.93 percent of magnesium hydroxide respectively, and its difference in strength and quality from the standard was not plainly stated on its label. The United States Pharmacopoeia provides that milk of magnesia shall contain not less than 7 percent of magnesium hydroxide.

It was alleged to be misbranded in that the label statements "Milk of Magnesia

* See also Nos. 805, 806, 807.

U. S. P.," and "Contains not less than 7% * * * of Magnesium Hydroxide," were false and misleading since the article did not comply with the specifications of the United States Pharmacopoeia.

On August 24, 1942, a plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$40.

816. Adulteration of ampuls of strontium bromide, triple distilled water, iron and arsenic, sodium iodide, Lactosan, and Solution Sal-Ar-Sodide. U. S. v. Cornelius L. Johnson (Haarlem Research Laboratories). Plea of guilty. Total fine, \$325. (F. D. C. No. 5557. Sample Nos. 24371-E, 24373-E to 24376-E, incl., 24385-E, 24391-E, 28036-E, 34842-E.)

On August 5, 1942, the United States attorney for the Southern District of New York filed an information against Cornelius L. Johnson, trading as the Haarlem Research Laboratories at New York, N. Y., alleging shipment within the period from on or about the month of February, to on or about October 7, 1940, from the State of New York into the States of Pennsylvania, Maryland, and New Jersey of quantities of ampuls of the above-named drugs which were adulterated.

The strontium bromide was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess since it purported and was represented to contain 15½ grains of strontium bromide in each 10 cc., whereas it contained not more than 12.59 grains of strontium bromide per 10 cc.

The triple distilled water was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the National Formulary, and its quality or purity fell below the standard set forth in such compendium since its contained sulfates and chlorides, ingredients which are not found in the official product and contained oxidizable substances in excess of the amounts permitted by the Formulary and the residue from 100 cc. was greater than the maximum permitted, 0.002 gram, and its difference from such standard was not plainly stated on its label.

The 2 shipments of iron and arsenic were alleged to be adulterated in that their strength differed from that which they purported and were represented to possess since the article in one shipment purported and was represented to contain in each 5 cc., 7.75 milligrams of iron and 32 milligrams of arsenic, whereas it contained in 5 cc. not less than 10.7 milligrams of iron and not less than 97.9 milligrams of arsenic; and the article in the other shipment was represented to contain in each 10 cc., 15.5 milligrams of iron and 64 milligrams of arsenic, whereas it contained in each 10 cc., not less than 24 milligrams of iron and not less than 190 milligrams of arsenic.

The sodium iodide was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the National Formulary, and its quality and purity fell below the standard set forth therein since it was not a clear aqueous solution but contained flocculent precipitate and its difference from such standard was not plainly stated on its label.

The Lactosan was alleged to be adulterated in that its strength differed from, and its quality fell below that which it purported and was represented to possess, as it was represented to contain in each 2 cc., ¾ grain of casein and 9/10 grain of sodium phosphate, whereas it contained in each 2 cc., not more than 0.304 (¾/10) grain of casein, and not more than 0.370 (less than ¾) grain of sodium phosphate.

The Solution Sal-Ar-Sodide was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and represented to possess since it purported and represented to contain in each 20 cc., 31 grains of sodium salicylate and 31 grains of sodium iodide, whereas it contained in each 20 cc., not more than 26.2 grains of sodium salicylate and not more than 27.4 grains of sodium iodide.

On September 10, 1942, the defendant having entered a plea of guilty, the court imposed a fine of \$100 on each of the second and third counts of the information, which involved the ampuls of triple distilled water and the 5 cc. ampuls of iron and arsenic, and imposed a fine of \$25 on each of the remaining five counts, a total of \$325.

817. Adulteration and misbranding of digitalis leaves capsules. U. S. v. Philadelphia Capsule Co., Inc., and Joseph McManus. Pleas of nolo contendere. Defendants found guilty. Fines, \$250. (F. D. C. No. 7285. Sample No. 54329-E.)

On August 19, 1942, the United States attorney for the Eastern District of Pennsylvania filed an information against the Philadelphia Capsule Co., Inc.,